Remarks

Upon entry of the foregoing amendment, claims 15 and 24-55 are pending in the application. Applicants have canceled claims 1, 8, 13, 17-20, and 22 without prejudice or disclaimer. Applicants reserve the right to pursue the canceled subject matter in one or more continuing applications.

The specification has been amended to correct a clerical error in the first paragraph of the application (claim to priority). The filing date of one of the Provisional Applications to which the present application claims priority (60/176,926, filed on January 20, 2000) was erroneously omitted in the preliminary amendment filed by Applicants on December 12, 2001. This filing date correctly appears on the filing receipt. Additionally, Applicants have corrected a typographical error in the first paragraph of the application (claim to priority). U.S. Provisional Application No. 60/138,630 was improperly entered as 60/,138,630. Additionally, Applicants have removed several embedded hyperlinks present in the specification as requested by the Examiner (*see*, page 9 of Paper No. 0703). Hence, no new matter has been added by way of these amendments.

Election/ Restriction

Applicants would like to thank the Examiner for acknowledging the timely traversal of the restriction requirement. *See*, Paper No. 0703, page 2, "Election/Restriction" item. Applicants would also like to point out that, contrary to the Examiner's statement on page 2 of the pending Office Action, no amendments were introduced in original claims 1, 8, 13, 15, 17-20, and 22 in response to the Restriction Requirement (Paper No. 0303). *See*, Paper No. 0703, page 2, "Election/Restriction" item. Furthermore, claims 24-55 were added in response to the Restriction Requirement, not claims 24-57 as stated in the Office Action. *See*, Paper No. 0703, page 2, "Election/Restriction" item.

Additionally, Applicants respectfully request clarification of the status of the rejoinder between Group III and Group V requested on page 12 in the response to Restriction Requirement filed May 7, 2003, as the Examiner has not given any ruling on said rejoinder request.

Priority

Applicants acknowledge the priority date of March 19, 1999 attributed to the present application by the Examiner. *See*, Paper 0703, page 3, "Priority" item.

Objections to the Specification

The Examiner objected to the disclosure "because it contains embedded hyperlinks and/or other form of browser-executable code." *See*, Paper No. 0703, page 9, "Specification Objections" item. More particularly, the Examiner pointed to "a) page 17, line 13; b) page 30, line 4; c) page 1906, line 24". *See*, Paper No. 0703, page 9, "Specification Objections" item.

Applicants have hereby amended the specification to remove the embedded hyperlinks a) and b) indicated by the Examiner. However, no embedded hyperlink could be found on page 1906 of the present application. Applicants have scanned the remainder of the specification and are not aware of any other embedded hyperlinks. Should Applicants find any additional embedded hyperlinks, those will be removed accordingly.

Claim objections

Claims 30-35, 41-47, and 52-55 are objected to "due to the claims not further limiting the subject matter of claims 24-29, 36-40, and 48-51, respectively." *See*, Paper No. 0703, page 9, first paragraph. More particularly, the Examiner states that "the requirements of for example claims 30-35 are the literal translation of the limitations numerically and succinctly described in claims 24-29." *See*, Paper No. 0703, page 9, first paragraph.

Applicants respectfully traverse and disagree.

Preliminarily, Applicants respectfully submit that claims 24 and 30, 36 and 41, and 48 and 52 are independent claims. Therefore it is unclear why the Examiner asserts that claims 30, 41, and 52 must further limit the subject matters of claim 24, 36, and 48, respectively. Applicants further note that they are entitled to claim the invention using multiple claims, so long as the claim set as a whole clearly defines the subject matter of the invention. *See,* M.P.E.P. §2173.05(n). Furthermore, section 706.03(k) of the MPEP states:

> Inasmuch as a patent is supposed to be limited to only one invention or, at most, several closely related indivisible inventions, limiting an application to a single claim, or a single claim to each of the related inventions might appear to be logical as well as convenient. However, court decisions have confirmed applicant's right to restate (i.e., by plural claiming) the invention in a reasonable number of ways. Indeed, a mere difference in scope between claims has been held to be enough.

Applicants further note that it is routine and widely accepted in biotechnology patent practice to claim isolated proteins by an explicit recitation of the amino acid sequences as

well as those isolated from a corresponding deposited clone. Thus, Applicants respectfully request that objection to claims 30-35, 41-47, and 52-55 be reconsidered and withdrawn.

Claim Rejection under 35 U.S.C. §101/112 first paragraph

The Examiner has rejected claims 24-55 under 35 U.S.C. § 101 because the invention is allegedly not supported by a credible, substantial, and specific, or well-established utility. *See,* Paper No. 0703, page 4, fifth paragraph. More particularly, the asserted utilities are allegedly not specific because "the disclosed uses of these compositions are not specific and are generally applicable to any predicted polypeptide sequence that was derived from computational analyses of the cDNA sequence." *See*, Paper No. 0703, page 4, sixth paragraph.

Applicants respectfully disagree and traverse.

Applicants submit that "an applicant's assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement of 35 U.S.C. 101." M.P.E.P. § 2107.02(III)(A) at 2100-39; *see also, In re Langer*, 503 F.2d 1380, 1391, 183 USPQ 288, 297 (CCPA 1974). "Where an applicant has specifically asserted that an invention has a particular utility, the assertion cannot simply dismissed as 'wrong.'" M.P.E.P. § 2107 (III) B at 2100-40. "Office personnel should not begin by questioning the truth of the statement of utility. Instead, any inquiry must start by asking if there is any reason to question the truth of the statement of utility. This can be done by simply evaluating the logic of the statements made." *See*, M.P.E.P. § 2107.02 at 2100-39. Further, the PTO must accept the manner of making and using an invention disclosed in a specification "unless there is a reason for one of skill in the art to question the objective truth of the statement of utility or its scope." *In re Langer*, 183 U.S.P.Q. at 297; *see also, In re Marzocchi*, 58 C.C.P.A. 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971) and *Utility Examination Guidelines*, 66 Fed. Reg. 1092, 1098-99 (Jan. 5, 2001). Indeed, the Federal Circuit has characterized the standard for utility by indicating:

> The threshold of utility is not high: An invention is "useful" under section 101 if it is capable of providing some identifiable benefit. *See Brenner v. Manson*, 383 U.S. 519, 534 (1996); *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571 (Fed. Cir. 1992) ("To violate § 101 the claimed device must be totally incapable of achieving a useful result"); *Fuller v. Berger*, 120 F. 247, 275 (7th Cir. 1903) (the test for utility is whether the invention "is capable of serving any beneficial end").

Juicy Whip, Inc. v. Orange Bang Inc., 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999). Accordingly, the burden is on the Examiner to establish why it is more likely than not that one of ordinary skill in the art would doubt (*i.e.*, "question") the truth of the statement of utility. *See*, M.P.E.P. § 2107 at 2100-30; *In re Brana*, 51 F.3d 1560, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995); and, *In re Cortright*, 49 U.S.P.Q.2d 1464, 1466 (Fed. Cir. 1999). The Examiner must provide evidence sufficient to show that the statement of asserted utility would be considered "false" by a person of ordinary skill in the art. *See, id.* Such a *prima facie* showing must contain (1) an explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is not specific, substantial, and credible; (2) support for factual findings relied upon in reaching this conclusion; and (3) an evaluation of all relevant evidence of record, including utilities taught in the closest prior art. *See, id.* Moreover, if applicants have presented reasoning used in asserting a utility, the Examiner must present countervailing facts and reasoning sufficient to establish that a person of ordinary skill would not believe the Applicants' assertion of utility. *See, id.* For the reasons set forth below, the Examiner has not met the burden that is necessary to establish and maintain a rejection for lack of utility under 35 U.S.C. § 101.

More specifically, the Examiner asserts "[t]he asserted specific utilities are based upon homology/ identity to experimentally known sequences after translating the cDNA. It is noted that applicant(s) have stated in the response (filed May 7, 2003) that 'Gene No. 570 is 100% identical to delta-tubulin' and that it is homologous to tubulin Uni3 [Chlamydomonas reinhardtii], yet has failed to point to the specification for this disclosure. . . . Absent factual evidence, a percentage sequence similarity of less than 100% nor homology, is not deemed to reasonably support to one skilled in the art whether the biochemical activity of the claimed subject matter would be the same as that of such a similar known polypeptide." *See*, Paper No. 0703, paragraph bridging pages 4-5. Applicants respectfully traverse and disagree.

Applicants assert that specific, substantial, and credible utilities are disclosed in the specification for Gene No. 570 of the invention. Primarily, Applicants indicate that Gene No. 570 is described in Table 1A, row 10, page 91. It is further described in Table 1B, page 547, row 4 to page 548, row 1. Gene No. 570 is further described in Table 1C, page 1470, rows 7-46, and page 1471, rows 1-5. Gene No. 570 is further described in Table 1D, page 1763, row 18. Gene No. 570 is further described in Table 2, page 1876, row 6, wherein it is clearly

disclosed that the claimed protein is 100% identical to delta-tubulin. Gene No. 570 is further described in Table 3, page 2625, row 4 to page 2627, row 1. Gene No. 570 is further described in Table 4, at page 4118, row 13, page 4123, row 16, page 4128, row 6, page 4146, rows 20 and 22, and page 4148, rows 5 and 16.

Applicants reiterate that the presently claimed invention, polypeptides encoded by Gene No. 570, is 100% identical to delta-tubulin, as described on page 1876, Table 2, row 6. According to the Examiner's own statement, such a degree of homology is "deemed to reasonably support to one skilled in the art" that "the biochemical activity of the claimed subject matter would be the same as that of such a similar known polypeptide." Based on its homology, the claimed invention is likely to share some biological functions of tubulins. Combined with its tissue distribution in human microvascular endothelial cells, polypeptides of the claimed invention and antibodies to the claimed invention would be useful for the diagnosis, treatment and/or prevention of microtubule associated vascular disorders affecting endothelial tissues which include, but are not limited to, atherosclerosis, arteriosclerosis and stroke. *See,* U.S. Provisional Application Serial No. 60/125,359 filed March 19, 1999, page 33. Therefore, Applicants respectfully submit that the instant rejection of pending claims 24-55 under 35 U.S.C. § 101 is based on incorrect assumptions from the Examiner.

The Examiner further states that "it is unpredictable if the cDNA that encodes SEQ ID NO: 3177 will successfully encode a functional protein in that it is not indicated to be a full-length open reading frame." *See*, Paper No. 0703, page 5, second paragraph. Additionally, the Examiner asserts "no actual protein with a defined functionality or biological activity is disclosed thus no certainty to have a useful isolated product with which to perform the potential activity assays described in Table 1D for SEQ ID NO: 3177". *See*, Paper No. 0703, page 5, second paragraph. Applicants respectfully traverse and disagree.

Applicants respectfully point out to the specification, where Table 1A describes the "5' NT [nucleotide] of Start Codon" (column 9) and the "Last AA of ORF" (column 15), hereby describing the open reading frame corresponding to Gene No. 570 and encoding the HDPKC55 polypeptide of amino acid sequence SEQ ID NO: 3177. *See*, Table 1A, page 91, row 10. The polypeptide of amino acid sequence SEQ ID NO: 3177 has a deduced length of 453 residues. When considering the length of the claimed polypeptide and the fact that it is 100% identical with a known polypeptide (delta-tubulin), Applicants assert that one skilled in the art would find it more likely than not that the cDNA containing clone HDPKC55 is translated into a fully functional polypeptide and, moreover, that based on its homology the

claimed polypeptide is likely to share some biological functions of tubulins. Therefore, contrary to the Examiner's comments, the specification provides the coding region of Gene No. 570, the corresponding polypeptide sequence, and corresponding biological functions associated with said polypeptide.

Additionally, the Examiner asserts that the specification lacks specific utility because it includes "a further laundry list of diseases or disorders that are within the indications." *See*, Paper No. 0703, page 6, first paragraph. Applicants respectfully traverse and disagree.

Contrary to the Examiner's contention, the disclosure of several uses for the claimed invention does not negate the specificity of any one of those uses. Indeed, the M.P.E.P. at § 2107.02 states "[i]t is common and sensible for an applicant to identify several specific utilities for an invention . . .". Further, "[i]f applicant makes one credible assertion of utility, utility for the claimed invention as a whole is established." *Id. See also, In re Malachowski*, 189 U.S.P.Q. 432 (C.C.P.A. 1976); *Hoffman v. Klaus*, 9 U.S.P.Q.2d 1657 (Bd. Pat. App. & Inter. 1988). As stated above, the claimed invention would be useful for the diagnosis, treatment and/or prevention of microtubule-associated vascular disorders affecting endothelial tissues which include, but are not limited to, atherosclerosis, arteriosclerosis and stroke. Therefore, the Examiner's assertion is improper and immaterial in the present case.

The Examiner further states that "[t]he research contemplated by applicant(s) to characterize potential protein products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a 'real world' context or use." *See*, Paper No. 0703, page 6, second paragraph. Applicants respectfully traverse and disagree.

For the reasons stated above, Applicants respectfully assert that the claimed invention fully complies with the requirements of 35 U.S.C. §§ 101 and 112. In particular, Applicants have asserted that the claimed polypeptides are useful, for example, in the diagnosis, treatment, and/or prevention of microtubule-associated vascular disorders. *See supra.* As stated above, the polypeptide of the invention exhibits 100% amino acid sequence identity with δ-tubulin. By the Examiner's own accord, such a high degree of homology is deemed to reasonably support to one skilled in the art that the biochemical activity of the claimed subject matter would be the same as that of such a similar known polypeptide. *See*, Paper No. 0703, page 5, first paragraph. The role of tubulins in essential cellular processes is well

known in the art and, at the time the parent application to which the present application claims priority was filed, it was already believed that tubulins could be used as therapeutic targets in, for instance, the treatment of atherosclerosis, which is a vascular disorder affecting endothelial tissues. *See*, for example, the abstract of reference AH of the attached Supplemental Information Disclosure Statement (Chaldakov, G.N. (1982) *Atherosclerosis* 44(3):385-390). This hypothesis was recently confirmed by Micheletti *et al.* (2003), who showed that a tubulin-binding agent induced the alteration of endothelial cell morphology and resulted in the loss of blood vessel integrity in the case of tumor treatment. *See*, for example, Abstract of Reference AK in the attached Supplemental Information Disclosure Statement (Micheletti *et al.* (2003) *Cancer Res.* 63:1534-1537)[1].

Additionally, recent publications identified δ-tubulin as a centrosomal tubulin, which interacts with γ-tubulin and could regulate cellular functions such as microtubule nucleation or centriole/basal body duplication, both being essential steps in cellular proliferation. *See*, for instance, page 416, first paragraph of reference AJ of the attached Supplemental Information Disclosure Statement (Smrzka *et al.* (2000) *Curr. Biol.* 10:413-416)[1] or the Abstract of Reference AI in the attached Supplemental Information Disclosure Statement (Chang, P., and Stearns T. (2000) *Nature Cell Biol.* 2:30-35)[1]. Additionally, the specification reveals that the clone of the invention is expressed in human microvascular endothelial cells (*see*, specification, Table 4, at page 4118, row 13, page 4123, row 16, page 4128, row 6, page 4146, rows 20 and 22, and page 4148, rows 5 and 16). Consequently, it is reasonable to predict that the claimed polypeptides are useful, for instance, in the diagnosis and/or treatment of vascular disorders affecting the endothelial tissues. Applicants respectfully point to the M.P.E.P., which states "any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient, at least with regard to defining a 'substantial' utility." *See*, M.P.E.P. § 2107.01(I) at 2100-33 (emphasis added). Applicants assert that, first the disclosed uses of the polypeptides of the invention are not generally applicable to all proteins. Second, the use of the claimed polypeptides in the detection or treatment of a specific disease such as atherosclerosis is certainly a "real world", substantial use.

[1] These references, dated after the applicants' filing date, "can be used to substantiate any doubts as to asserted utility since it pertains to the accuracy of a statement already in the specification." *See e.g., In re Brana* 51 F.3d 1560, 1567 at n19 (Fed. Cir. 1995).

Furthermore, Applicants respectfully remind the Examiner that utility can exist for therapeutic inventions "despite the fact that an applicant is at a very early stage in the development of a pharmaceutical product or therapeutic regimen based on a claimed pharmacological or bioactive compound or composition." M.P.E.P. § 2107(III) at 2100-27. "Usefulness in patent law . . . necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans." *In re Brana*, 51 F.3d 1560, 1568 (Fed. Cir. 1995) (Emphasis added).

As for the Examiner's position that "a percentage sequence similarity of less than 100% is not deemed to reasonably support to one skilled in the art whether the biochemical activity of the claimed subject matter would be the same as that of such a similar known polypeptide[.]" (*see*, Paper No. 0703, page 5, first paragraph), Applicants respectfully point out to the Notice of the Federal Register of January 5, 2001, Vol. 66, No. 4, which refused to "adopt a *per se* rule rejecting homology-based assertions of utility" because no "scientific evidence that homology-based assertions of utility are inherently unbelievable or involve implausible scientific principles" was provided. Therefore, Applicants submit that homology-based assertions of utilities are not *per se* implausible. Additionally, Applicants point out that the asserted utilities for Gene No. 250 of the present invention are based on perfect sequence homology. Therefore, according to the Examiner's comment, such degree of homology is sufficient to support the asserted utilities.

In view of the arguments presented above, Applicants respectfully submit that the utility asserted in the specification for the claimed polypeptides HDPKC55 is indeed, specific, substantial and/or well established. Applicants therefore request that the rejection of claims 24-55 under 35 U.S.C. § 101 be reconsidered and withdrawn

Claims 24-54 are also rejected under 35 U.S.C. § 112, first paragraph. *See*, Paper 0703, page 7, second paragraph. Specifically, the Office Action asserts "since the claimed invention is not supported by a specific, substantial, and credible utility, or, alternatively, a well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention." *See,* Paper No. 0703, page 7, second paragraph.

For the reasons discussed above in response to the rejection under 35 U.S.C. § 101, the claimed invention is supported by a specific, substantial and credible asserted utility. The Examiner "should not impose a 35 U.S.C. § 112, first paragraph, rejection grounded on a 'lack of utility' basis unless a 35 U.S.C. §101 rejection is proper." M.P.E.P. § 2107 (IV) at 2100-36. Therefore, because the claimed invention complies with the utility requirement of 35 U.S.C. § 101, the rejections under 35 U.S.C. § 112, first paragraph, based on the alleged lack of utility of the claimed invention, should be withdrawn. Accordingly, Applicants respectfully request that the rejection of claims 24-55 under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

Claim Rejection under 35 U.S.C. § 112 first paragraph (written description)

A. The Examiner has rejected claims 50-55 under 35 U.S.C. § 112, first paragraph for alleged lack of written description. *See,* Paper No. 0703, page 7, fourth paragraph. More particularly, it is stated "claims 36-55 are directed to specific fragment peptides that are not supported by the specification. In addition, the specification lacks support for any specific fragment or specific percent identity to SEQ ID NO: 3177, or any other sequence" *See*, Paper No. 0703, page 7, fourth paragraph.

Applicants respectfully disagree and traverse.

Primarily, Applicants respectfully point to the specification, more particularly to the extensive description of fragments of polynucleotide sequence SEQ ID NO:X (in the present case SEQ ID NO: 580), fragments of polypeptide sequence SEQ ID NO:Y (in the present case SEQ ID NO: 3177), and fragments of the cDNA contained in the Clone ID NO:Z, shown in column number 3 of Table 1A (in the present case Clone ID NO:203960) and of the polypeptides it encodes, which can be found at paragraph [212], page 4202 to paragraph [225], page 4207. As for the description of variants of SEQ ID NO: 3177, and of other sequences, Applicants respectfully point out to paragraph [170], page 4186 to paragraph [173], page 4188; paragraph [175], page 4188 to paragraph [178], page 4190; and paragraph [181], page 4191 to paragraph [184], page 4192. Therefore, contrary to the Examiner's statement, the specification as filed provides ample support for specific fragments of the polypeptide of the invention.

Accordingly, Applicants respectfully request that the rejection of claims 36-55 under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

B. The Examiner has rejected claims 24-55 under 35 U.S.C. § 112, first paragraph for alleged lack of written description. *See,* Paper No. 0703, page 7, fifth paragraph. More particularly, it is stated "the claims are directed to encompass proteins corresponding to sequences of 90% or 95% identity to the overall of SEQ ID NO: 3177. The specific 10% or 5% that are not identical to the elected sequence are represented by the claim are not supported by the specification." *See*, Paper No. 0703, page 8, first paragraph. The Examiner further states "[a]lthough the sequence itself distinguishes the structural features of the nucleic acid, sequences, beyond exact identity (be it in entirety or to contiguous fragments) of the elected SEQ ID NO: 3177, are included but not disclosed as to written description." *See*, Paper No. 0703, page 8, first paragraph (emphasis added).

Applicants respectfully disagree and traverse.

The test for the written description requirement is whether one skilled in the art could reasonably conclude that the inventor has possession of the claimed invention in the specification as filed. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991); and M.P.E.P. § 2163.02. The Federal Circuit recently re-emphasized the well-settled principle of law that "[t]he written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [they] invented what is claimed,'" *Union Oil Co. v. Atlantic Richfield Co.*, 208 F.3d 989, 54 U.S.P.Q.2d 1227 (Fed. Cir. 2000). While the applicant must "blaze marks on trees," rather than "simply [provide] the public with a forest of trees," an Applicant is not required to explicitly describe each of the trees in the forest. *See Unocal*, 208 F.3d at 1000. The Court emphasized the importance of what the person of ordinary skill in the art would understand from reading the specification, rather than whether the specific embodiments had been explicitly described or exemplified. Indeed, as the court noted, "the issue is whether one of skill in the art could derive the claimed ranges from the patent's disclosure." *Unocal*, 208 F.3d at 1001 (emphasis added). This goes against the Examiner's statement that sequences, beyond exact identity of the elected SEQ ID NO: 3177, are included but not disclosed, or, in other words, that they need to be specifically enumerated in order to meet the written description requirement.

In an analysis of written description under 35 U.S.C. § 112, first paragraph, the Examiner bears the initial burden of presenting a *prima facie* case of unpatentability. This burden is only discharged if the Examiner can present evidence or reasons why one skilled in

the art would not reasonably conclude that Applicants possessed the subject matter as of the priority date of the present application. *See, In re Wertheim*, 541 F.2d 257, 262, 191 U.S.P.Q.2d 90, 96 (C.C.P.A. 1976); and M.P.E.P. § 2163.04. In the instant case, Applicants respectfully submit that the Examiner has not met this burden.

Applicants respectfully disagree with the Examiner and submit that one skilled in the art would reasonably conclude that Applicants had possession of the polypeptides encompassed by the rejected claims in the present application as filed. Applicants further submit that the Examiner has underestimated both the teaching of the present application and the level of skill in the art on the priority date of the present application.

Applicants submit that the specification does, indeed, provide adequate written description to enable one of skill in the art to make useful predictions as to the identities of the claimed polypeptides. Specifically, the specification provides ample disclosure of the characteristics of the HDPKC55 polypeptides and provides a detailed analysis of the methods needed to obtain, for instance, polypeptides exhibiting 90% or 95% homology with SEQ ID NO: 3177. *See*, specification, at, for instance, paragraphs [170]-[173], pages 4186-4188, paragraphs [175]-[178], pages 4188-4190, and paragraphs [181]-[184], pages 4191-4192. Accordingly, one skilled in the art, enlightened by teachings of the present application (particularly, for example, the sequences associated with the HDPKC55 clone), could readily envision countless polypeptide sequences that comprise the specified polypeptides. For example, the skilled artisan could clearly envision each of the polypeptides that are 95% identical to the polypeptide of SEQ ID NO: 3177 as a polypeptide with 1, 2 or up to 5 amino acid substitutions along its length. Indeed, nothing more than a basic knowledge of the genetic code and what is described in the specification would be required for the skilled artisan to identify every single one of the polypeptides that are 90% or 95% identical to the amino acid sequence of SEQ ID NO: 3177. Clearly, such knowledge is well within what is expected of the skilled artisan.

Further, the instant claims do not require the claimed sequences to possess any particular activity or characteristic beyond the described sequence, and the subject matter of what is claimed is fully supported by the specification. § 112 requires no more. *See Unocal*, 208 F.3d at 1000; M.P.E.P. § 2163.02. Therefore, the Examiner's argument that "[e]ach variation of the 5% or 10% non-identical, results in a new and independent sequence that does not reliably result in similar or identical biological activities as result for example from

altered folding patterns[.]" (*see*, Paper No. 0703, page 8, first paragraph) is irrelevant in the context of the written description requirements.

The Examiner further alleges "[t]hus the instant claims are directed to encompass peptide sequences that correspond to sequences from other species, mutated fragment sequences, allelic variants, splice variants, and so forth. None of these additional sequences meet the written description provision of 35 USC 112, first paragraph." *See*, Paper No. 0703, page 8, first paragraph. Applicants respectfully traverse and disagree.

Applicants respectfully indicate that the claimed invention is specifically directed to human secreted proteins (*see*, Abstract), and in particular, polypeptides corresponding to the selected clone of the invention, HDPKC55. As for other sequences (mutated fragment sequences, allelic variants sequences, or splice variants), Applicants respectfully submit that, for the reasons stated above, and because Applicants have provided the core structural feature of the polypeptides of the inventions, namely SEQ ID NO: 3177, the disclosure provides adequate written description support for the scope of the claims, particularly at pages 4183-4207, paragraphs [163]-[225] of the specification.

Finally, Applicants assert that, in order to fulfill the written description requirement and contrary to the Examiner's comment, it is not necessary to have "experimentally isolated the claimed 'isolated protein'" (*see*, Paper No. 0703, page 7, last paragraph). As stated above, the test for the written description requirement is whether one skilled in the art could reasonably conclude that the inventor had possession of the claimed invention based on the specification as filed. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991); M.P.E.P. § 2163.02. Indeed, as the Federal Circuit has noted, "the issue is whether one of skill in the art could derive the claimed ranges from the patent's disclosure." *Union Oil Company of California v. Atlantic Richfield Company*, 208 F.3d 989, 54 U.S.P.Q. 2d 1227 (Fed. Cir. 2000) (emphasis added). Applicants assert that by providing the core structural feature of the polypeptides of the inventions, namely SEQ ID NO: 3177, the disclosure provides adequate written description support.

Therefore, Applicants submit that the pending claims fully meet the written description requirements of 35 U.S.C. § 112, first paragraph, and respectfully request that the Examiner's rejection of claims 24-55 under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

B. The Examiner has rejected claims 30-35, 41-47, and 52-55 under 35 U.S.C. § 112, first paragraph for alleged lack of written description. *See,* Paper No. 0703, page 8, second paragraph. More particularly, it is stated "[t]he specification provides insufficient written description to support the biological deposits of the claims." *See*, Paper No. 0703, page 8, fourth paragraph.

Applicants respectfully traverse and disagree.

Applicants respectfully point to the specification, particularly to paragraph [64] at page 30, where it is stated "The ATCC deposits were made pursuant to the terms of the Budapest Treaty on the international recognition of the deposit of microorganisms for the purposes of patent procedure." Furthermore, Applicants provide herewith a statement complying with the requirements of 37 C.F.R. § 1.808.

The undersigned attorney of record hereby states:

1. ATCC Deposit No. 203960 containing human cDNA encoding the Secreted Protein HDPKC55, clone HDPKC55 was deposited with the American Type Culture Collection (ATCC), now located at 10801 University Boulevard, Manassas, VA 20110-2209, U.S.A. on April 26, 1999, in compliance with the provisions of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.

2. I hereby assure the United States Patent and Trademark Office and the public that (a) all restrictions on the availability to the public of a sample of the above-mentioned deposited plasmid will be irrevocably removed upon issuance of a United States patent of which the plasmid(s) is a subject; (b) the above-mentioned deposited plasmids will be maintained for a period of at least five years after the most recent request for the furnishing of a sample of the plasmid was received by the ATCC and, in any case for a period of at least 30 years after the date of deposit or for the enforceable life of such patent, whichever is longer; (c) should the above-mentioned deposited plasmid become non-viable or mutated or otherwise incapable of being furnished by the depository upon request due to the condition of the deposit, the plasmid will be replaced by the Applicants; and (d) access to the above-mentioned deposited plasmid will be available to the Commissioner during the pendency of the patent application or to one determined by the Commissioner to be entitled to such plasmid under 37 C.F.R. § 1.14 and 35 U.S.C. § 122.

Applicants assert that the above statement is sufficient to overcome the Examiner's rejection and respectfully request that the rejection of claims 30-35, 41-47, and 52-55 under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

Conclusion

Applicants respectfully request the amendments and remarks of the present response be entered and be made of record in the file history of the present application. In view of the foregoing amendments and remarks, Applicants believe they have fully addressed the Examiner and that this application is now in condition for examination. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the examination of this application.

Applicants believe that there are no fees due in connection with the filing of this paper. However, should a fee be due, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

Dated: December 16, 2003

Respectfully submitted,

By 

Janet M. Martineau
Registration No.: 46,903
HUMAN GENOME SCIENCES, INC.
9410 Key West Avenue
Rockville, Maryland 20850
(301) 315-2723

KKH/JMM/FR/ba